

Notice of Allowability

Application No.

09/764,050

Examiner

Joyce Tung

Applicant(s)

OKAMOTO ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/8/2004.
2. ☒ The allowed claim(s) is/are claims 1-26.
3. ☒ The drawings filed on July 31, 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☒ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

REASONS FOR ALLOWANCE

The applicant's response filed 10/08/2004 has been entered. Claims 1-26 are pending.

1. The following is an examiner's statement of reasons for allowance:

Concerning claims 1-19, no prior art has been found teaching or suggesting the method for dry detection/quantification of target nucleotide chains in which a hybrid is formed between the target nucleotide chains and a probe nucleotide chain and a fluorescence dye acts on the hybrid, thereby emits fluorescence or increases its fluorescence intensity for the detection/quantification.

Concerning claims 20-26, no prior art has been found teaching or suggesting the method for dry detection/quantification of multi-stranded nucleotide chains in which the multi-stranded nucleotide chains with fluorescence dye in a sample solution is placed on a clean substrate for drying and then the fluorescence emitted from the dried sample is measured.

The closest prior art is the reference of Sutherland et al. (WO 8706956, issued November 19, 1987) and in view of Johann et al. (6,277,628, issued August 21, 2001). Sutherland et al. disclose a waveguide coated with single-stranded probe nucleic acid in which the single-stranded sample nucleic acid is allowed to react with the probe in the presence of intercalant fluorescence dyes (See pg. 5, fifth paragraph). Johann et al. disclose a method and a composition for detecting the levels of a plurality of biomolecular probes in a sample. The Cy5-5' labeled 59mer was used to fill a glass bead capillary array. The array was washed and then dried and scanned with a confocal fluorescence microscope (See column 8, lines 22-32). There is no motivation to combine these two references to make the instant invention because Sutherland et al. and Johann et al. involve completely different systems of fluorescence dyes for detection in that Johann et al. use labeled probe which is detected, in this regard, such fluorescence markers or dyes emit

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fluorescence regardless of whether a hybrid forms and the fluorescence dye do not react with the hybrid, and Sutherland et al. indicate that measurement of nucleic acid hybridizations could be carried out without the necessity to pre-prepare labeled probes. Thus, the instant invention is allowed over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 571 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

3. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Joyce Tung *J. Tung*
December 22, 2004

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

12/27/04